

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

ELIZABETH PROVENCHER,)
Plaintiff,)
v.) No. 2:23-cv-00222-JAW
SANOFI US SERVICES INC. F/K/A,)
SANOFI-AVENTIS U.S. INC., et al.)
Defendants.)

ORDER ON MOTION FOR LEAVE TO AMEND COMPLAINT

The plaintiff in a products liability case transferred to this court from a multidistrict litigation moves for leave to amend her complaint. The Court denies the request because the plaintiff has not shown that good cause exists to justify amending the complaint in contravention of a judicial scheduling order or that her motion is not unduly delayed and unfairly prejudicial to defendants.

I. PROCEDURAL BACKGROUND

Elizabeth Provencher, alongside thousands of other plaintiffs, filed a complaint against Sanofi U.S. Services Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Aventis U.S. LLC (Sanofi Defendants) as part of a multidistrict litigation that was consolidated with the March 31, 2017 filing of a Master Complaint. *See In re: Taxotere (Docetaxel) Prods. Liab. Litig.* (E.D. La., MDL No. 2740); *Jt. Designation of R. for MDL Transfer* (ECF No. 5) (*Jt. Transfer R.*), Attach. 5, *Master Long Form Compl. and Demand for Jury Trial*. The Master Complaint alleged the Sanofi Defendants created a cancer treatment drug that caused plaintiffs to develop

permanent alopecia. *Id.* The United States District Court for the Eastern District of Louisiana conducted pretrial proceedings including general discovery and bellwether trials. *Jt. Transfer R.*, Attach. 115, *Case Mgmt. Order No. 39 (Summ. of MDL 2740 Proceedings Upon Suggestion of Remand or Transfer) (MDL Proceedings Summ.)*.

The MDL plaintiffs sought leave to amend the master Complaint three times. *See Jt. Transfer R.*, Attach. 45, *Order and Reasons (Order Denying Pls.' Mot. for Leave to File Pls.' Third Am. Master Long-Form Compl.) (Am. Compl. Denial)*. The MDL Court granted the first two motions to amend, but on December 11, 2019, the MDL Court denied the third, which sought to redefine the injury. *Id.* This made the Second Amended Master Complaint filed September 27, 2018 the operative master pleading. *See id.; id.*, Attach. 26, *Second Am. Master Long Form Compl. and Demand for Jury Trial*.

Along with the master complaint, each plaintiff had to file a short-form complaint; in hers, Ms. Provencher alleged she suffered and will continue to suffer from disfiguring permanent alopecia because of receiving chemotherapy with the Sanofi Defendants' product, Taxotere. *Compl.* (ECF No. 1). This short-form complaint, filed on November 14, 2018, adopted all allegations and claims set forth in the master long-form complaint, namely strict products liability under a failure to warn theory, negligence, negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, and fraud and deceit. *Id.* at 4.

During the multidistrict litigation, Judge Milazzo and Magistrate Judge North of the Judicial Panel on Multidistrict Litigation entered over 100 pretrial and case

management orders. *See Pretrial Orders* (ECF No. 4). The parties jointly designated 116 general documents from the multidistrict litigation docket and five case-specific documents from *Provencher v. Sanofi-Aventis U.S. LLC*, Nos. 2:18-cv-10992 and 2:16-md-740 to be included in the record on transfer to this court. *See Jt. Transfer R.; Jt. Designation of General MDL Records* (ECF No. 6). Relevant here, the parties designated a May 11, 2020 pretrial order that set forth deadlines for amending short-form complaints, and stipulations that followed from it. *See Jt. Transfer R.*, Attach. 51, *Pretrial Order No. 105*; *id.*, Attach. 60, *Stipulation Regarding Pretrial Order No. 105*; *id.*, Attach. 73, *Second Stipulation Regarding Pretrial Order No. 105* (setting January 15, 2021 as the deadline to file a motion to amend).

On May 12, 2023, Judge Milazzo transferred Ms. Provencher's case from the Eastern District of Louisiana to this Court for further case-specific proceedings. *See Transfer Order* (ECF No. 7); *Jt. Transfer R.*, Attach. 102, *Case Mgmt. Order No. 33*; *id.*, Attach. 104, *Case Mgmt. Order No. 34*; *id.*, Attach. 111, *Case Mgmt. Order No. 34C*.

On August 7, 2023, Ms. Provencher moved for leave to amend her complaint, *Mot. to Amend Compl.* (ECF No. 22) (*Pl.'s Mot.*), and included the proposed amended complaint. *Id.*, Attach 2., *Ex. Proposed Am. Compl.* (*Proposed Am. Compl.*). On August 28, 2023, the Sanofi Defendants opposed. *Resp. in Opp'n* (ECF No. 23) (*Defs.' Opp'n*). On September 11, 2023, Ms. Provencher replied. *Reply to Resp. to Mot.* (ECF No. 25) (*Pl.'s Reply*). Thereafter, on October 5, 2023 and February 8, 2024, the Sanofi Defendants submitted supplemental authority. *Suppl. Authority in Supp. of Sanofi's*

Opp'n (ECF No. 26) (*Defs.' Suppl. Authority*); *Second Suppl. Authority in Supp. of Sanofi's Opp'n* (ECF No. 30) (*Defs.' Second Suppl. Authority*).

II. THE PARTIES' POSITIONS

A. Elizabeth Provencher's Motion for Leave to Amend Complaint

Ms. Provencher contends that the Court ought to grant leave to amend the complaint because her amendment is not made in bad faith, unduly delayed, or futile and “would serve justice and promote judicial efficiency.” *Pl.'s Mot.* at 1.

Ms. Provencher asserts the proposed amended complaint would “serve as [her] live Complaint in this case,” and “does not add any new parties or causes of action.” *Id.* at 2. “Rather,” she says that she “requests leave to re-plead so that she has a full and fair right to present and litigate her claims in this case.” *Id.* She also avers that the amended complaint is:

[N]ecessary to provide further and/or additional basis to litigate that [her] cause(s) of action have either not yet accrued, did not begin to accrue until a date within the applicable statute of limitations, and/or, at best, did not begin to accrue until after the product label was finally updated on or about December 11, 2015 (following multiple previous changes/updates to the prescribing information) to include for the first time the word permanent when it came to hair loss or alopecia.

Id. at 2-3 (emphasis in original). “Moreover,” Ms. Provencher says, “the Amended Complaint further details Defendants’ fraudulent concealment and/or intentional omission of material facts.” *Id.* at 3.

B. The Sanofi Defendants' Objection and Opposition

The Sanofi Defendants argue there are “multiple reasons” the Court “should deny Ms. Provencher’s Motion.” *Defs.' Opp'n* at 1.

First, they contend that “Ms. Provencher’s motion inexplicably asks the Court to grant an identical request made and denied by the MDL because amendment (in 2019) would fundamentally alter plaintiffs’ injury definition, undo the MDL court’s work, and result in extreme prejudice to Defendants.” *Id.* The Sanofi Defendants allege that although Ms. Provencher “does not acknowledge it,” her motion “Duplicates a Rule 15 motion filed and lost in the MDL.” *Id.* at 4.

In support, the Sanofi Defendants quote the transferring court’s order that denied the plaintiffs’ third motion for leave to amend. *See id.* at 5. Therein, the MDL court concluded that allowing plaintiffs to amend their complaint to change their injury definition would “negate a significant amount of the work’ done in the MDL, would require defendants to prepare a different defense based on the new injury definition (and result in revised expert reports and new expert depositions), and would ‘moot[]’ certain rulings from the MDL court.” *Id.* (quoting *Am. Compl. Denial*). The Sanofi Defendants add that the MDL court denied the request “[b]ecause the proposed amendment would ‘cause serious prejudice to Defendants’ and undo the MDL court’s work.” *Id.* (citing *Am. Compl. Denial* at 5).

The Sanofi Defendants cite *Ellis v. United States*, 313 F.3d 636 (1st Cir. 2002) for the proposition that “[t]he orderly functioning of the judicial process requires that judges of coordinate jurisdiction honor one another’s orders and revisit them only in special circumstances.” *See Defs.’ Opp’n* at 6 (quoting *Ellis*, 313 F.3d at 646). The Sanofi Defendants then contend that there “are no special circumstances here” that

warrant granting an amendment that “would effectively upend the seven years of work conducted in the MDL.” *Id.*

Second, the Sanofi Defendants argue the motion “fails to explain why, despite being given the opportunity by the MDL court, [Ms. Provencher] failed to add allegations regarding fraud and the statute of limitations to her Short Form Complaint.” *Id.* at 1. They add that Ms. Provencher “should not be given that chance now, several years later.” *Id.*

Third, the Sanofi Defendants argue that “amendment would be futile” because even if granted, “[Ms. Provencher’s] fraud claims still fail [Federal Rule of Civil Procedure] 9(b)’s pleading standard and her claims are still time-barred.” *Id.* at 1. They contend “Ms. Provencher’s proposed amendments fail to connect Ms. Provencher’s personal alleged injury to a single factual allegation of a specific event, statement, or conduct by Sanofi; to when and where the conduct occurred; to who engaged in the conduct; to whom it was directed; or why it was improper.” *Id.* at 9 (citing *Thao v. LH Hous., LLC*, No. 2:21-CV-00240-JDL, 2022 U.S. Dist. LEXIS 142135, at *9 (D. Me. Aug. 10, 2022) (quoting *Dumont v. Reily Foods Co.*, 934 F.3d 35, 38 (1st Cir. 2019))). Therefore, Defendants argue, “allowing amendment would be futile” as the complaint would still be “insufficient to state a claim for fraud.” *Id.*

Further, the Sanofi Defendants argue that if the amended complaint were accepted, Ms. Provencher’s claims would still fall outside of the statute of limitations. *Id.* The Sanofi Defendants assert that “Maine does not recognize the discovery rule in a products case like this one,” therefore when Ms. Provencher became “aware of

her injury or its cause is irrelevant because ‘a cause of action accrues ‘at the time a judicially cognizable injury is sustained.’” *Id.* (quoting *Novak v. Mentor Worldwide LLC*, 287 F. Supp. 3d 85, 90 (D. Me. 2018)). They say that “Ms. Provencher already testified that her hair regrew and fell out again by 2011,” so her filing suit in 2018 was “at least a year too late.” *Id.* at 10. Defendants concede there is a fraudulent concealment exception to the six-year statute of limitations but argue “Ms. Provencher includes no such facts in her Proposed Complaint, and the exception accordingly cannot apply.” *Id.*

C. Elizabeth Provencher’s Reply

Ms. Provencher replies that “[d]espite Sanofi’s suggestions to the contrary, the MDL Court did not make any specific ruling prior to remand that is binding on this Court.” *Pl.’s Reply* at 1. She argues that “Defendants are neither prejudiced nor have they suffered any surprise by the allegations in [her] proposed Amended Complaint.” *Id.* For “these additional reasons and because good cause exists,” she believes her motion should be granted. *Id.*

Regarding the statute of limitations, Ms. Provencher argues that since “Sanofi’s label was not changed to warn and inform [her] or her healthcare providers regarding risk of ‘**permanent** hair loss’ until December 2015 . . . the applicable statute of limitations could not begin to run on Plaintiff’s claim” before then. *Id.* at 1-2 (emphasis in original).

She then argues that the MDL Court denying leave to file a third amended master complaint to change the injury definition “was only **that** Court’s

interpretation and does not preclude this Court from reaching a different conclusion.” *Id.* at 2 (emphasis in original). Ms. Provencher adds that the “[M]DL Court did not allow individual plaintiffs in the MDL, including Plaintiff, the opportunity to make any additional, further or other allegations regarding the underlying issue.” *Id.* (emphasis in original). Instead, she asserts, the only opportunity to amend her complaint to add particularized facts was for purposes of arguing the statute of limitations, *id.* (citing *Joint Designation of R.*, Attach. 23, *Case Management Order* at 8), and “came at a point in time when case-specific discovery had hardly commenced in Plaintiff’s case. Plaintiff’s deposition was not concluded until nearly two years later on February 14, 2023, and this remains the only deposition conducted to date in this case.” *Id.* Ms. Provencher interprets this to mean she “has not had the opportunity at all to amend her Complaint to address the crux of the matter” and “that there is no way any Court can impute or imply knowledge to an individual patient regarding Taxotere-induced permanent hair loss before Sanofi claims it first knew of and actually warned about this risk.” *Id.*

Ms. Provencher adds that “the MDL Court’s Transfer Order specifically states ‘[a]ll deadlines for Plaintiffs to amend their individual complaints without leave of court have passed.’” *Id.* (citing *MDL Proceedings Summ.* at 4). To Ms. Provencher, “[t]hat sentence specifically contemplates that individual plaintiffs upon remand, including Plaintiff, will seek leave to amend in transferee courts.” *Id.* at 2-3.

Ms. Provencher then turns to prejudice or surprise and contends none is present here as her “proposed Amended Complaint will not alter any facts,” “the

parties are not going to have to retain any additional experts should Plaintiff's Motion to Amend be granted since no case-specific expert discovery has been conducted to date," and the amended complaint will "not result in the need to conduct any additional discovery beyond what is already necessary." *Id.* at 3. She says that "[a]ny arguments to the contrary are red herrings." *Id.*

III. LEGAL STANDARD

Federal Rule of Civil Procedure 15 concerns amended and supplemental pleadings. FED. R. CIV. P. 15. Rule 15 allows amending as a matter of course within twenty-one days. FED. R. CIV. P. 15(a)(1). "In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave." FED. R. CIV. P. 15(a)(2). Rule 15 also states that the Court "should freely give leave when justice so requires." *Id.*

"But this does not mean . . . that a trial court must mindlessly grant every request for leave to amend.' Indeed, 'a district court may deny leave to amend when the request is characterized by undue delay, bad faith, futility, [or] the absence of due diligence on the movant's part.'" *Universal Trading & Inv. Co. v. Bureau for Representing Ukrainian Ints. in Int'l & Foreign Cts.*, 87 F.4th 62, 80 (1st Cir. 2023) (internal citation omitted) (quoting *Nikitine v. Wilmington Tr. Co.*, 715 F.3d 388, 390 (1st Cir. 2013)); *accord Forman v. Davis*, 371 U.S. 178, 182 (1962). "So, too, the court may deny the request if the proposed amendment 'would serve no useful purpose.'" *Calderon-Serra v. Wilmington Tr. Co.*, 715 F.3d 14, 20 (1st Cir. 2013) (quoting *Aponte-Torres v. Univ. of P.R.*, 445 F.3d 50, 58 (1st Cir. 2006)).

In making its determination whether to grant a motion for leave to amend, a district court is given broad discretion, *Forman*, 371 U.S. at 182, and “must consider the totality of the circumstances.” *Nikitine*, 715 F.3d at 390.

For example, Rule 15 motions to amend pleadings must also be read in conjunction with the requirements of Federal Rule of Civil Procedure 16, which requires that the district court enter a scheduling order setting certain deadlines. *See* FED. R. CIV. P. 16(b)(1). Those deadlines may be modified “only for good cause and with the judge's consent.” FED. R. CIV. P. 16(b)(4). “[O]ur case law clearly establishes that Rule 16(b)’s ‘good cause’ standard, rather than Rule 15(a)’s ‘freely give[n]’ standard, governs motions to amend filed after scheduling order deadlines.” *Flores-Silva v. McClintock-Hernández*, 710 F.3d 1, 3 (quoting *Trans-Spec Truck Serv. v. Caterpillar Inc.*, 524 F.3d 315, 327 (1st Cir. 2008)); *accord United States ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188, 194 (1st Cir. 2015). The Court of Appeals for the First Circuit has also “noted that Rule 16’s ‘good cause’ standard ‘focuses on the diligence (or lack thereof) of the moving party more than it does on any prejudice to the party-opponent.’” *Somascan, Inc. v. Philips Med. Sys. Nederland, B.V.*, 714 F.3d 62, 64 (1st Cir. 2013) (quoting *Flores-Silva*, 710 F.3d at 3).

“It is settled that, ‘[r]egardless of the context, the longer a plaintiff delays, the more likely the motion to amend will be denied, as protracted delay, with its attendant burdens on the opponent and the court, is itself a sufficient reason for the court to withhold permission to amend.’” *Somascan*, 714 F.3d at 64 (quoting *Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004)). “Appreciable delay alone, in

the absence of good reason for it, is enough to justify denying a motion for leave to amend.” *Calderon-Serra*, 715 F.3d at 20; *see also Kay v. N.H. Dem. Party*, 821 F.2d 31, 34 (1st Cir. 1987) (per curiam) (affirming a finding of undue delay when three months had elapsed).

IV. DISCUSSION

A. Ms. Provencher Has Not Demonstrated Good Cause to Modify the MDL Scheduling Order

The parties’ arguments center around the application of Federal Rule of Civil Procedure 15, particularly Rule 15(a)(2)’s freely given standard. *See FED. R. CIV. P. 15(a)(2)*.

However, First Circuit “case law clearly establishes that Rule 16(b)’s ‘good cause’ standard, rather than Rule 15(a)’s ‘freely give[n]’ standard, governs motions to amend filed after scheduling order deadlines.” *Flores-Silva*, 710 F.3d at 3 (quoting *Trans-Spec*, 524 F.3d at 327); *accord EV3, Inc.*, 802 F.3d at 194.

In the case at bar, the MDL court set a scheduling order deadline that explicitly addressed motions to amend. *See Jt. Transfer R.*, Attach. 51, *Pretrial Order No. 105*. This scheduling order states: “This Order applies to all Plaintiffs in MDL No. 2740 who intend to amend their Short Form Complaints in light of the Court’s rulings related to statute of limitations.” *Id.* at 1. The Court set the deadline for filing amended short-form complaints to 180 days after the Court order. *Id.* at 2. The parties then filed a stipulation that extended this deadline to January 15, 2021. *Jt. Transfer R.*, Attach. 60, *Stipulation Regarding Pretrial Order No. 105* at 1. In this stipulation, the parties agreed that “[n]o further requests for extension [for leave to

amend] shall be permitted unless by consent of all parties or for good cause shown by an individual Plaintiff to justify an extension in their specific case.” *Id.*

Put simply, the MDL Court set a January 15, 2021 deadline for amending complaints. To amend her complaint after that, Ms. Provencher either needed the consent of the Sanofi Defendants or to show good cause, as required by Rule 16 once the scheduling order deadline has passed. Ms. Provencher’s motion for leave to amend is not a consent motion and she missed the deadline, so she must show good cause. In this broader litigation, several district courts that received sister cases transferred from the MDL Court have found that similar attempts to amend were prohibited by Pretrial Order 105. *See, e.g., Maxwell v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-696-ACA, 2023 U.S. Dist. LEXIS 193253 (N.D. Ala. Oct. 27, 2023); *DelGiorno v. Sanofi US Services Inc.*, No. 2:23-cv-4264-CFK, 2024 U.S. Dist. LEXIS 14905 (E.D. Penn. Jan 29, 2024); *cf. MDL Proceedings Summ.* at 4 (“All deadlines for Plaintiffs to amend their individual complaints without leave of court have passed”).¹ Accordingly, in this Court’s view, Rule 16(b)’s good cause standard is the appropriate standard under which to consider Ms. Provencher’s motion. *See Flores-Silva*, 710 F.3d at 3.

“The ‘good cause’ standard focuses on both the conduct of the moving party and the prejudice, if any, to the nonmovant.” *Miceli v. JetBlue Airways Corp.*, 914 F.3d 73, 86 (1st Cir. 2019) (citing *O’Connell v. Hyatt Hotels of P.R.*, 357 F.3d 152, 155 (1st Cir. 2004)). In determining whether good cause exists, “the moving party’s diligence

¹ The Sanofi Defendants provided other examples. *See* *Defs.’ Suppl. Authority*; *Defs.’ Second Suppl. Authority*.

or lack of diligence serves as the ‘dominant criterion.’” *Id.* (quoting *O’Connell*, 357 F.3d at 155. “[T]he longer a plaintiff delays, the more likely the motion to amend will be denied, as protracted delay, with its attendant burdens on the opponent and the court, is itself a sufficient reason for the court to withhold permission to amend.” *Steir*, 383 F.3d at 12. “Nor should a court be expected to look kindly upon a plaintiff who seeks belatedly to amend her complaint based on ‘information that [she] had or should have had from the outset of the case.’” *Miceli*, 914 F.3d at 86 (quoting *Trans-Spec*, 524 F.3d at 327).

The totality of the circumstances, which the Court must consider, *see Nikitine*, 715 F.3d at 390, do not support a finding that Ms. Provencher has been diligent and meets this high bar. Quite to the contrary. The record demonstrates protracted delay without even an attempt to explain it away, compounded by the fact Ms. Provencher seeks to amend based on information she knew or should have known long ago.

Ms. Provencher argues that she “has not had the opportunity at all to amend her Complaint to address the crux of the matter”: “that there is no way any Court can impute or imply knowledge to an individual patient regarding Taxotere-induced permanent hair loss before Sanofi claims it first knew of and actually warned about this risk . . . in December 2015.” *Id.* at 2. She also says that the “MDL Court did not allow individual plaintiffs . . . the opportunity to make any additional, further or other allegations” beyond particularized facts to argue the statute of limitations. *Id.* (emphasis in original).

As noted above, however, several other district courts have not interpreted the MDL's order that way. The Court joins that consensus and finds Ms. Provencher's argument unavailing. Ms. Provencher did not move to amend by January 15, 2021, the time frame set by the MDL Court, and has not even argued why she could not have done so.

Ms. Provencher also says she wants to update her complaint to include facts surrounding the Sanofi Defendants' actions that limited her ability to know Taxotere caused her injury. The Court is unconvinced that these facts, which are meant to move the date of the injury, are not directly tied to the MDL Court's order setting a deadline for amending complaints, and which explicitly addressed statute of limitation issues. After all, it seems reasonable to treat her attempt to move the date of the injury as nothing more than an attempt to push back the date from which the statute of limitations would toll. In other words, her amendments were covered by the MDL Court's order and Ms. Provencher must demonstrate good cause for her motion to be granted.

“When a litigant seeks leave to amend in defiance of a deadline delineated in a scheduling order, the rationale for applying an elevated good cause standard is both obvious and pragmatic.” *EV3, Inc.*, 802 F.3d at 194. “Were a district court powerless to enforce such deadlines, scheduling orders would be little more than aspirational statements, to be disregarded by the parties whenever compliance proves inconvenient.” *Id.* (citing *O'Connell*, 357 F.3d at 155). “Properly deployed, the elevated good cause standard puts teeth into Rule 16(b) scheduling orders and

‘preserves the integrity and effectiveness of [such] scheduling orders.’” *Id.* (quoting *O’Connell*, 357 F.3d at 155). “Rule 16(b)’s less amendment-friendly standard acts as one of the sticks through which compliance with a scheduling order is enforced,” and the Court utilizes it here to ensure the scheduling orders of the MDL court are not for naught. *Id.*; *see also Ellis*, 313 F.3d at 646 (“The orderly functioning of the judicial process requires that judges of coordinate jurisdiction honor one another’s orders and revisit them only in special circumstances”); Stanley A. Weigel, *The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts*, 78 F.R.D. 575, 575–76 (1978) (“If transferor judges were permitted to upset the rulings of transferee judges, the result would be an undermining of the purpose and usefulness of transfer under Section 1407”).

B. Ms. Provencher’s Request to Amend is Unduly Delayed

As neither party discussed Rule 16(b)(4)’s good cause standard, and in the excess of caution, the Court also reviews Ms. Provencher’s request to amend under the more lenient Rule 15(a)(2) standard and concludes that Ms. Provencher’s argument still fails.

Under Rule 15(a)(2), “[i]n general, leave should be freely given if, in the court’s view, ‘justice so requires.’” *Miceli*, 914 F.3d at 86 (quoting FED. R. CIV. P. 15(a)(2)). However, “the largesse that Rule 15(a)(2) contemplates is not without limits. The rule ‘does not mean . . . that a trial court must mindlessly grant every request for leave to amend.’” *Calderon-Serra*, 715 F.3d at 19 (quoting *Aponte-Torres*, 445 F.3d at 58). “A district court may deny leave to amend when the request is characterized

by ‘undue delay, bad faith, futility, [or] the absence of due diligence on the movant’s part.’” *Id.* at 19 (quoting *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006). “So, too, the court may deny the request if the proposed amendment ‘would serve no useful purpose.’” *Id.* (quoting *Aponte-Torres*, 445 F.3d at 58).

Even if the Court accepts Ms. Provencher’s position that the MDL Court’s Pretrial Order No. 105 was only limited to amendments relating to the statute of limitations and accepts that her current amendments would not contravene such an order, Ms. Provencher has still failed to explain her lengthy delay in filing for leave to amend.

The record indicates a lengthy, unexplained delay. Ms. Provencher filed her short-form complaint on November 14, 2018. The Plaintiffs filed the Second Master Complaint on September 27, 2018, and the MDL accepted it shortly thereafter. The MDL denied the third amendment to the Master Complaint on December 11, 2019. The pretrial order limiting additional amendments was issued on May 11, 2020. *See Jt. Transfer R.*, Attach. 51, *Pretrial Order No. 105*. Even if Ms. Provencher’s amendments were not covered in that order, it should have put her on notice that “many Plaintiffs have begun amending, or intend to amend, their individual Short Form Complaints.” *Id.* at 1. Ms. Provencher does not explain why, amidst this discussion of amending complaints, she did not amend her own to include the “actions,” “inactions,” and “misrepresentations” that occurred before and around the time that the Sanofi Defendants changed “their product label for Taxotere *on or about December 11, 2015*,” as she attempts to do now. *Pl.’s Mot.* at 2 (emphasis supplied).

Ms. Provencher did not file her motion for leave to amend until August 7, 2023. That is three months after the case was transferred to this Court and over four-and-a-half years after she filed her short form complaint. “[W]hen ‘a considerable period of time has passed between the filing of the complaint and the motion to amend, courts have placed the burden upon the movant to show some valid reason for [her] neglect and delay.’” *Nikitine*, 715 F.3d at 390–91 (citing *Hayes v. New Eng. Millwork Distrib., Inc.*, 602 F.2d 15, 19–20 (1st Cir. 1979)). Here, there is at minimum a three-month delay and at maximum nearly a five-year delay, yet Ms. Provencher offers no good reason for either.

“Importantly, ‘[t]his is not a case of new allegations coming to light following discovery, or of previously unearthed evidence surfacing.’” *Id.* at 390-91 (citing *Villanueva v. United States*, 662 F.3d 124, 127 (1st Cir. 2011) (per curiam)). As the Court of Appeals for the First Circuit concluded in a case where there was a nine-month delay:

It is, rather, a case in which a court reasonably could have concluded . . . that the plaintiff was scrambling to devise “new theories of liability [] based on the same facts pled in his original complaint,” *Tiernan v. Blyth, Eastman, Dillon & Co.*, 719 F.2d 1, 4 (1st Cir.1983); *see Hayes*, 602 F.2d at 20—theories that could and should have been put forward in a more timeous fashion. Without any explanation as to why these new theories were not seasonably advanced, the delay in formulating them looms large.

Id. This reasoning extends to this case.

“Appreciable delay alone, in the absence of good reason for it, is enough to justify denying a motion for leave to amend.” *Calderon-Serra*, 715 F.3d at 20 (citing *Kay*, 821 F.2d at 34). Thus, the Court concludes that Ms. Provencher has acted with

undue delay and should not be given leave to amend her complaint. *See, e.g., Nikitine*, 715 F.3d at 391 (affirming finding of undue delay when nine months had elapsed); *Villanueva*, 662 F.3d at 127 (same when four months had elapsed); *Kay*, 821 F.2d at 34 (same when three months had elapsed).

Before moving on, the Court notes that it has considered the fact that Ms. Provencher's case began in a consolidated multidistrict litigation, which can complicate procedural matters. For example, Ms. Provencher's "deposition was not concluded until nearly two years later [than the deadline for amending short-form complaints] on February 14, 2023, and this remains the only deposition conducted to date in this case." *Pl.'s Reply* at 2. Based on this, Ms. Provencher argues that she "has not had the opportunity at all to amend her Complaint to address the crux of the matter." *Id.*

The Court finds this argument unpersuasive; Ms. Provencher points to no information gathered in her deposition that is a "new allegation[] coming to light following discovery, or [] previously unearthed evidence surfacing." *Nikitine*, 715 F.3d at 391. Absent that or any other explanation, the Court finds Ms. Provencher has failed to show a valid reason for her neglect and delay. This counsels against granting her motion for leave to amend, and the Court therefore denies her request. *Cf. Calderon-Serra*, 715 F.3d at 20 ("The appellants strive to persuade us that they had good reason for the delay. To this end, they point to the fact that this case was twice passed from judge to judge and vaguely assert that these reassignments justified their laggardly pace. We are not convinced").

C. Ms. Provencher's Request to Amend is Unfairly Prejudicial to the Sanofi Defendants

The Sanofi Defendants rely on the MDL Court's order denying the collective Plaintiffs' third amended master long-form complaint to contend granting Ms. Provencher's motion should be denied because it would cause unfair prejudice. *See* *Defs.' Opp'n* at 5 (citing *Am. Compl. Denial*). Specifically, they argue it would negate a significant amount of work, require them to prepare a different defense, and lead to additional discovery. They also contend that granting the motion would effectively upend seven years of work performed by the MDL Court and even moot some of the MDL Court's rulings. *Id.* at 5-6.

Ms. Provencher disagrees there is any prejudice or surprise. She argues "the parties are not going to have to retain any additional experts should Plaintiff's Motion to Amend be granted since no case-specific expert discovery has been conducted to date," and that the amended complaint will "not result in the need to conduct any additional discovery beyond what is already necessary." *Pl.'s Reply* at 3.

In denying the Plaintiffs' proposed third amended master long-form complaint, the MDL Court reasoned:

This Court agrees with Defendants that an amendment to the Long Form Complaint would be inappropriate at this time. The parties and the Court have been operating under Plaintiffs' original definition of their alleged injury since Plaintiffs adopted it in their original master complaint filed on March 31, 2017. Magistrate Judge North used the definition in resolving certain discovery disputes. For example, when Plaintiffs requested a 30(b)(6) deposition (presumably the first of several) and asked Sanofi to produce a representative who could discuss reports of "persistent alopecia" with Taxotere, Sanofi objected to the broad nature of this request. Judge North ruled that "persistent alopecia" meant alopecia remaining six months after chemotherapy.

This Court also adopted Plaintiffs' definition in its summary judgment rulings on statute of limitations issues. Indeed, Plaintiffs' own expert, Dr. Laura Plunkett, adopted this definition in her expert report, writing that the medical literature generally defines irreversible alopecia as "hair loss that is still seen six months after treatment has ended."

Am. Compl. Denial at 4 (footnotes omitted). The MDL Court continued its analysis and reasoned that:

If the Court were to allow Plaintiffs to amend at this late stage, this would negate a significant amount of the work that has been done in this MDL. Defendants would undoubtedly want to revise certain expert reports and conduct supplemental depositions, and certain rulings from the Court would be mooted. It is apparent that the main reason Plaintiffs wish to amend the Long Form Complaint at this juncture is to save cases that are otherwise subject to dismissal for being filed too late. By redefining the injury and adding allegations of fraudulent concealment, Plaintiffs would not only delay the start of prescription but also require Defendants to defend against the application of *contra non valentem* based on Sanofi's alleged fraudulent concealment.

Id. at 4-5. The MDL Court then concluded by saying it would "not allow Plaintiffs to make these unduly belated amendments that would cause serious prejudice to Defendants," or to "backtrack" on the "presumably . . . informed decision to define their injury the way they originally did." *Id.* at 5.

Paragraph 96 of Ms. Provencher's proposed amended complaint states that "[t]here is no single definition of Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiff and other patients, including but not limited to other plaintiffs in the MDL." *Proposed Am. Compl.* ¶ 96. This modification is precisely the change the MDL Court denied. *See Am. Compl. Denial* at 4-5. Insofar as Ms. Provencher says that "this decision was only **that** Court's interpretation and does not

preclude this Court from reaching a different conclusion,” *Pl.’s Reply* at 2 (emphasis in original), the Court is unconvinced. “The orderly functioning of the judicial process requires that judges of coordinate jurisdiction honor one another’s orders and revisit them only in special circumstances.” *Ellis*, 313 F.3d at 646. As discussed above, the record does not support finding that special circumstances exist; instead, it supports finding there was undue delay.

Beyond undermining judicial efficiency, the Court agrees with the MDL Court that amending the complaint would cause unfair prejudice to Defendants. Even after the Court considers that fact-specific discovery is still underway, it remains clear that changing the underlying definition of injury would result in “discovery with additional costs, a significant postponement of trial, and a likely major alteration in trial strategy and tactics.” *Acosta-Mestre v. Hilton Int’l of P.R., Inc.*, 156 F.3d 49, 52 (1st Cir. 1998). As the MDL Court stated, “Defendants would undoubtedly want to revise certain expert reports and conduct supplemental depositions.” *Am. Compl. Denial* at 4. To the degree the Court accepts that it must decide whether this amended complaint would cause unfair prejudice, it agrees with the MDL Court and concludes it would. The Court therefore denies Ms. Provencher’s motion.

V. SUMMARY

The Court is unconvinced that the lenient standard under Federal Rule of Civil Procedure 15(a)(2) is appropriate in this case given that Ms. Provencher’s motion was made after a scheduling deadline was set and had passed. In such a case, courts in this circuit apply the more stringent good cause standard found in Federal Rule of Civil Procedure 16(b). Ms. Provencher’s motion to amend fails under the Rule 16(b)

standard because the totality of the circumstances here demonstrates protracted delay and a lack of diligence. Ms. Provencher's motion also fails under the more lenient Rule 15(a)(2) standard because it was filed with undue delay and to allow it would both be unfairly prejudicial to the Sanofi Defendants—as it would require them to spend additional time and effort updating discovery and trial strategy—and undermine the judicial efficiency created by multidistrict litigation discovery. As justice does not require it, Ms. Provencher's motion is denied.

VI. CONCLUSION

The Court DENIES Elizabeth Provencher's Motion to Amend Complaint (ECF No. 22).

SO ORDERED.

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
UNITED STATES DISTRICT JUDGE

Dated this 29th day of March, 2024